IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE

Planned Parenthood of Tennessee and North Mississippi, et al., Plaintiffs, v. Herbert H. SLATERY III, et al., Defendants.	Case No. 3:20-cv-00740 JUDGE CAMPBELL

**DECLARATION OF STEVEN JOFFE, M.D., M.P.H.,
IN SUPPORT OF PLAINTIFFS' MOTION FOR
TEMPORARY RESTRAINING ORDER AND/OR PRELIMINARY INJUNCTION**

Steven Joffe, M.D., M.P.H., declares the following:

1. I submit this declaration in support of Plaintiffs' motion for temporary and/or preliminary injunctive relief to enjoin enforcement of Tenn. Code Ann. § 39-15-218 (effective October 1, 2020) ("the Act").

2. As set forth more fully below, I am a Professor of Medical Ethics at the University of Pennsylvania Perelman School of Medicine, where I serve as Interim Chair of the Department of Medical Ethics and Health Policy. I have spent two decades researching medical ethics issues that arise in the course of medical practice, including extensive research on the specific question of informed consent. Until last year, I also practiced children's cancer medicine and bone marrow transplantation at the Children's Hospital of Philadelphia.

3. Based on my expertise and two decades of research in medical ethics and informed consent, as well as my two decades of medical practice, it is my opinion that the Act, if implemented, would undermine informed consent for patients seeking medication abortion and

mislead patients concerning the safety and efficacy of medication abortion "reversal." In so doing, the Act forces physicians to violate fundamental tenets of medical ethics; puts patients at serious risk of making harmful errors in their decision-making; and steers patients toward experimental, unproven medical treatments, the safety and effectiveness of which have not been established.

Background

4. My curriculum vitae is attached hereto as Exhibit A.

5. I currently hold a number of positions at the University of Pennsylvania Perelman School of Medicine, including Interim Chair of the Department of Medical Ethics and Health Policy, Chief of the Division of Medical Ethics, Founders Professor of Medical Ethics and Health Policy, and Professor of Pediatrics. As a part of these appointments, I lead the activities of the Department of Medical Ethics and Health Policy, with supervisory responsibility for the Department's research and teaching. I also serve as Director of the Department's postdoctoral fellowship training programs in Medical Ethics, and am currently the Co-Director of the Cancer Control Program at the Abramson Cancer Center.

6. Prior to joining the University of Pennsylvania, I practiced pediatric hematology/oncology at Boston Children's Hospital and the Dana-Farber Cancer Institute, both affiliated with Harvard Medical School. I also completed four fellowships, including a medical ethics fellowship at Harvard Medical School and a professional ethics faculty fellowship at the Center for Ethics and Professions at Harvard University. Until last year, I practiced medicine at the Children's Hospital of Philadelphia, where I cared for children undergoing bone marrow transplants for cancer and other serious diseases.

7. I have authored and co-authored numerous peer-reviewed research articles and chapters in medical textbooks, including on issues of medical ethics and informed consent. In

addition, I regularly speak on informed consent and other ethical issues that arise in clinical research and practice to a variety of different audiences, including physicians, at national conferences, as well as at seminars at medical centers and universities.

8. In my previous role as a member for more than ten years of the Institutional Review Board at Dana-Farber Cancer Institute, an affiliate of Harvard Medical School, I have formally reviewed, approved, and monitored biomedical and behavioral research involving human subjects in order to protect the rights and welfare of research subjects.

9. I have also been a member of or chaired numerous institutional and national ethics committees. I am a member of the Pediatric Ethics Subcommittee of the Food and Drug Administration and the Bioethics Committee of the Children's Oncology Group. I also serve on a number of institutional and academic advisory committees, including two committees tasked with overseeing COVID19-related research and the Conflict of Interest Committee, at the Perelman School of Medicine. I also previously served on the Ethics Committee at the Children's Hospital of Philadelphia (2013-2019), the Ethics Advisory Committee of Boston Children's Hospital (2000-2013), and the Ethics Advisory Committee (2000-2013, co-chair 2001-2009) and the Institutional Review Board (1998-2012) at the Dana-Farber Cancer Institute.

10. In addition to my medical degree, I have a Master's of Public Health in epidemiology, which is the study of disease in human populations. Epidemiology focuses on the distribution and causes of disease in human populations, seeks to identify risk factors for disease, and conducts studies to determine optimal treatment approaches for clinical practice and for preventive medicine. Among other things, the discipline of epidemiology involves training in the design, conduct, and analysis of human research.

The Act

11. I have reviewed Tenn. Code. Ann. § 39-15-218 and understand that it imposes certain requirements on physicians (and their agents) performing abortions in Tennessee and on facilities in which "more than fifty (50) elective abortions" were performed during the previous calendar year.

12. Tennessee is not the first state to pass this type of requirement. I previously served as an expert in a case challenging a similar law passed by the Arizona legislature in 2015 and provided testimony in that case in support of the plaintiffs' motion for a preliminary injunction. In that case, the State ultimately agreed to a preliminary injunction and the case was subsequently dismissed after the Arizona legislature repealed the portions of the law concerning medication abortion "reversal" that the plaintiffs challenged.

13. I understand that, as it is commonly provided, the medication abortion protocol involves two medications: mifepristone first, followed by misoprostol twenty-four to forty-eight hours later. I further understand that, as detailed below, the claim that medication abortion can be "reversed," "avoided," or "ceased" once begun has been rejected as unsupported by the medical evidence by both the preeminent national professional organization of obstetricians and gynecologists ("OBGYNs") (the American College of Obstetricians and Gynecologists or "ACOG") as well as the primary association of family planning researchers (the Society of Family Planning or "SFP").

14. I further understand that the Act requires that, at least forty-eight hours prior to providing a medication abortion, the same physician who is to provide the mifepristone must inform the patient that "[i]t may be possible to reverse the intended effects of a chemical abortion utilizing mifepristone if the woman changes her mind" and that "information on and assistance with reversing the effects of a chemical abortion utilizing mifepristone is available on the

department of health website." I further understand that the law requires any waiting room and patient consultation room used by patients obtaining abortions (whether medication or procedural abortions) to display a sign stating, in three-quarter inch font and boldfaced type: "Recent developing research has indicated that mifepristone alone is not always effective in ending a pregnancy. It may be possible to avoid, cease, or even reverse the intended effects of a chemical abortion utilizing mifepristone if the second pill has not been taken. Please consult with a healthcare professional immediately." I understand that such language must also be provided to medication abortion patients in writing alongside medical discharge instructions.[1]

15. I further understand that the Tennessee Department of Health is required, by December 30, 2020, to publish on its website information "designed to inform the woman of the possibility of reversing the effects of a chemical abortion utilizing mifepristone if the woman changes her mind" and must provide "information on and assistance with the resources that may be available to help reverse the effects of a chemical abortion."[2,3]

16. In order to understand why the Act seriously undermines informed consent for patients seeking abortions—and requires physicians to violate medical ethics in a number of other respects, including by forcing physicians to endorse an unproven and potentially unsafe medical intervention and mislead patients about the demonstrated efficacy or safety of that intervention—it is important to first understand the general principles of informed consent (for both proven medical treatments, like medication abortion, and unproven treatments, such as abortion

[1] Tenn. Code Ann. §§ 39-15-218(b), (c), (e), (f).
[2] Tenn. Code Ann. § 39-15-218(h).
[3] I understand that the Tennessee Department of Health has not yet published information about "reversing" medication abortion on its website.

"reversal"). I will thus first explain the basic principles of informed consent, and then apply those principles to the Act.

General Principles of Medical Ethics and Informed Consent

17. Medical ethics is a system of moral principles encompassing standards of professional conduct within the practice of medicine and medical research, developed primarily for the benefit of patients and research participants. The central tenets of medical ethics are: (1) respect for patients' autonomy as individuals, including the obligation to act on patients only with their informed consent; (2) acting in patients' best interests, as they define those interests ("beneficence"); (3) avoiding harm to patients ("non-maleficence"); and (4) promoting justice to patients and to society.[4] Ethical physician behavior recognizes that patients' rights and interests are paramount.

18. By adhering to principles of medical ethics, physicians build a relationship of trust with their patients. As the current COVID-19 crisis has made clear, it is crucial to public health and to the integrity of the medical profession that patients be able to trust that their physicians are providing them with accurate, evidence-based information. That trust is undermined if patients come to believe that their physicians are mere spokespersons for particular views that are not grounded in solid scientific evidence.

19. According to the standard conception of medical ethics, informed consent is fundamental to ethical practice. Patients have the right to control their own bodies and lives, which means that ultimately the decision about what medical treatment they get is theirs to make. Informed consent is the mechanism by which patients exercise their autonomy and choose whether to authorize medical interventions or courses of treatment

[4] Tom L. Beauchamp & James F. Childress, *Principles of Biomedical Ethics* (6th ed. 2009).

20. Generally speaking, the goal of the informed consent process is to allow patients to make decisions—consistent with their wishes, values, and priorities—about their own medical treatment, and to ensure that these decisions are based on accurate information about the goals and nature of the treatment in question, the risks and benefits of that treatment, and the alternatives. Said differently, the goal of the process is to ensure that a patient does not undergo any treatment until they have made a fully informed decision, based on accurate information, that the treatment in question is right for them and that the treatment's benefits to them outweigh its risks.

21. Informed consent is also integral to maintaining a relationship of trust between patient and physician. According to the American Medical Association Code of Medical Ethics, "[t]ruthful and open communication between physician and patient is essential for trust in the relationship and for respect for autonomy," and "[p]atients have the right to receive information and ask questions about recommended treatments so that they can make well-considered decisions about care. Successful communication in the patient-physician relationship fosters trust and supports shared decision making."[5]

22. To make informed consent possible, a patient must be given accurate and relevant information about a particular procedure so that the patient can make the right decision for herself. Thus, the *goal* of informed consent is not simply to ensure that a physician provides certain specified information; rather, the provision of accurate and relevant information by a physician is the necessary prerequisite for the patient to make her own informed decisions about what treatment to obtain, if any.

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[5] AMA Code of Medical Ethics, *Opinion 2.1.1* (Nov. 14, 2016), https://www.ama-assn.org/delivering-care/ethics/informed-consent.

23. Under standard medical practice, physicians are expected to exercise appropriate medical judgment during the informed consent process regarding what information should be provided and how it should be provided, with the aim of helping the patient to make an informed decision that is right for her. This aim guides how the physician frames information to ensure that informed consent is facilitated and not impeded.

24. While the physician is ultimately responsible for ensuring that patients have obtained accurate and relevant information to make an informed decision, ethical practice does not require that the information be communicated directly by the treating physician, as other members of the healthcare team may also be expert at guiding a patient through the informed decision making process. Doctors work collaboratively within a team, and so long as the treating physician oversees the process and provides medical recommendations and information based on the patient's desires and values, as elicited through the informed consent process, informed consent information may ethically be provided by other members of the healthcare team.

25. In order to facilitate a patient's informed consent, one of the most fundamental obligations the physician has is to ensure patients are provided with truthful and accurate information.

26. It would be antithetical to the purpose of informed consent, and a violation of medical ethics, for a healthcare provider to knowingly give misleading and inaccurate information to a patient during the informed consent process. If a provider were to give a patient misleading or inaccurate information, the provider would be manipulating the patient's decision, thus depriving her of the ability to make an authentic decision based on her own values and preferences.

27. Put more simply, providing *in*accurate information increases the likelihood that a patient will make a decision that is not right for her, violating not only ethical principles of

autonomy but also of doing no harm (non-maleficence) and acting in the patient's best interests (beneficence).

28. Similarly, informed consent requires physicians to use their best medical judgment as to what information is material and relevant to a patient's decision making. Patients count on their healthcare providers to exercise medical judgment in presenting relevant information in a clear, straightforward fashion. Patients who do not have medical expertise need to be able to digest relevant information and use it to inform their decision. It is therefore important that healthcare providers not overwhelm or confuse patients with extraneous or irrelevant information.

29. Thus, given the physician's paramount duty to provide only truthful and material information to their patient, and to do so in a way that facilitates rather than impedes informed consent, a physician must be able to make reasonable professional judgments about the validity and materiality of information when deciding what to tell patients during the informed consent process.

Applications of These Principles to the Act

30. In my opinion, the Act forces physicians to violate these elemental principles of medical ethics and informed consent and fundamentally threatens the informed consent process by overriding the physician's medical judgment and compelling physicians to tell patients information that is not supported by credible, scientific evidence. It is also my opinion that the Act, by forcing physicians to provide inaccurate, misleading, and unsupported information to their patients, damages the trust central to the patient-provider relationship, which is fundamental to the ethical provision of medical care. Furthermore, it is my opinion that the Act requires physicians to violate medical ethics by forcing them to endorse and direct patients to treatments, the safety and efficacy of which have not been established.

31. Moreover, it is my opinion that the Act undermines informed consent, creating a grave risk that a patient may make errors in their decision-making that will prove harmful to them, by forcing physicians to communicate to patients, forty-eight hours prior to taking mifepristone, an inaccurate, misleading message that suggests that the patient need not be certain in her decision before proceeding with an abortion because the effects of mifepristone may be "reversed," "ceased," or "avoided."[6]

The Act Undermines the Informed Consent Process

32. In my opinion, the Act is harmful to patients because it forces physicians to communicate a message to their patients that suggests to them that they need not be firm in their decision to terminate the pregnancy before beginning their abortion. This is directly contrary to physicians' ethical obligations as part of the informed consent process. Because the goal of the informed consent process is to ensure that a patient does not undergo any course of treatment that the patient does not truly want, it would undermine the purpose of informed consent for a physician to communicate things (or be forced to communicate things) that encourage a patient to delay making a final decision about whether to undergo a course of treatment until after the treatment has begun.

33. This is particularly so when patients are seeking a treatment with a desired outcome that may have significant implications for their life, like abortion, and when there is no question that, once women start the procedure, in most—or even many—cases (contrary to what the Act seems to imply) their pregnancy will end. In such a situation, it is crucial during the informed consent process to emphasize that the patient should be certain in her decision before she begins

[6] Tenn. Code Ann. § 39-15-218(f).

the medication abortion process. The Act undermines this important message and therefore impedes the informed consent process.

34. Thus, in my opinion, the Act's required message could mislead women into beginning the abortion process before they have come to a firm decision, based on the inaccurate assumption that an option for reversal exists should they change their mind. The Act's requirements thus impede informed consent and violate the principles of beneficence (acting in the patient's best interest) and non-maleficence (doing no harm to the patient).

35. I understand that, in the sterilization context, the ACOG Ethics Committee has recommended that physicians emphasize to patients, prior to sterilization procedures, that the procedures are permanent. This makes sense from an informed consent perspective, even though it is generally accepted in medicine that some sterilization procedures, such as tubal ligations and vasectomies, may be effectively reversed for some people.[7] However, because such procedures may well not be effectively reversed for any given person, it is necessary for physicians to ensure that patients have come to a complete decision to undergo permanent sterilization prior to undergoing such a procedure, by emphasizing the likely permanence of the procedure during informed consent.

36. It would make no sense in such instances to also require a physician to state that sterilization procedures "may be reversible," even though that statement may be accurate for some people. Doing so would undermine the informed consent process and confuse a patient who is being simultaneously told that the procedure should be "considered permanent and not reversible."

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[7] The Mayo Clinic, *Tubal Ligation Reversal* (Mar. 4, 2020), https://www.mayoclinic.org/tests-procedures/tubal-ligation-reversal/about/pac-20395158.; The Mayo Clinic, Vasectomy Reversal (July 25, 2020), https://www.mayoclinic.org/tests-procedures/vasectomy-reversal/about/pac-20384537.

One would not want to encourage the possibility that a patient who is uncertain about his or her decision to undergo sterilization would nevertheless proceed because he or she has been told that it might be reversible.

37. This logic applies all the more in the medication abortion context, where there is no reliable evidence demonstrating that "reversal" is possible for *any* patients. It is crucial that the informed consent process emphasize that the patient must come to a full and final decision about her treatment before it begins. The informed consent process simply must not mislead her into believing she may delay final decision-making until after beginning the medication abortion process.

38. I am aware of no other area of medicine in which physicians are forced by law to tell their patients about unproven or experimental treatments of unknown safety and efficacy.

The Act Damages the Trust Between Patient and Healthcare Provider

39. As noted above, physicians have an ethical obligation to communicate truthful and honest information to their patients. This is so not only because patients have the right to receive accurate information about their care so that they may make informed decisions, but also because trust is crucial to the physician-patient relationship. A relationship of trust ensures that patients feel comfortable asking any questions they have and revealing personal information about themselves and their lives. This level of open communication is crucial to the provision of ethical medical care, and especially to informed consent, ensuring that the physician understands the patient's needs and values, and that the patient feels comfortable asking any questions they may have.

40. The Act undermines this trust by forcing physicians to communicate medical information that the physician knows is inaccurate, misleading and, as discussed in more detail below, not supported by scientific evidence. *See infra* ¶¶ 44–56.

41. Patients rely on their physicians to provide them with accurate information to support informed decision-making. When a physician presents information to a patient about the treatment options that are available and the expected outcomes, the patient expects that information to be grounded in evidence and in the physician's honest understanding, and to constitute information the physician believes is material to the patient's decision-making process. This makes sense—healthcare providers have the information that patients need in order to make informed decisions about medical treatment. Patients, most of whom lack medical training or expertise, must be able to rely on their chosen healthcare providers to give them clear, appropriate, relevant, and scientifically accurate information. For a physician to do otherwise would violate patient expectations and undermine patient trust.

42. The Act undermines this trust by forcing physicians to direct patients to unproven medical treatments that physicians do not believe are in the patient's best interest. Indeed, the Act forces physicians to communicate messages that physicians believe may actually *harm* patients, thereby undermining the informed consent process.

43. In my opinion, the problems presented by the Act cannot be avoided merely by the physician telling the patient that the government thinks the reversal option exists even though the physician personally disagrees. Merely raising the idea of "reversal" wrongly encourages the patient to consider a possibility for which there is no evidence. To simply disavow the Act's mandated communications also fails to restore respect for the patient's autonomy because it still requires her to hear, from a health care professional in whom she needs to be able to trust, a medical

message that is not based on scientific evidence. In addition, providing contradictory messages about medical information to a layperson is virtually certain to cause confusion and distract them from the essential information they need to make a decision. Provoking this kind of profound confusion is precisely what healthcare providers should avoid doing during the informed consent process.

The Act Requires Provision of Inaccurate Information

44. Recently, ACOG and SFP issued a joint practice bulletin/clinical guidelines for OBGYNs concerning medication abortion, which noted:

> In the very rare case that patients change their mind about having an abortion after taking mifepristone and want to continue the pregnancy, they should be monitored expectantly. There is no evidence that treatment with progesterone after taking mifepristone increases the likelihood of the pregnancy continuing. However, limited available evidence suggests that use of mifepristone alone without subsequent administration of misoprostol may be associated with an increased risk of hemorrhage.[8]

45. In explaining that there is no evidence that progesterone treatment increases the likelihood that a pregnancy will continue after taking mifepristone, the ACOG/SFP guidelines refer to articles,[9] analyzing the claim made in two papers by Drs. George Delgado and Mary Davenport,[10] that administering progesterone to a patient can "reverse" the effects of mifepristone.

46. I have read both of the papers by Delgado and Davenport. That these two papers are the only publications in the medical literature of which I am aware that claim to demonstrate

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[8] ACOG Practice Bulletin Number 225, Vol. 136, No. 4 (October 2020).

[9] Daniel Grossman & Kari White, *Abortion "Reversal"—Legislating without Evidence*, 379 New Eng., J. of Med.1491, (Oct. 18, 2018).; Daniel Grossman et al., *Continuing pregnancy after mifepristone and "reversal" of first-trimester medical abortion: a systematic review*, 92 Contraception 206 (2015).

[10] George Delgado & Mary L. Davenport, *Progesterone use to reverse the effects of mifepristone*, 46 The Annals of Pharmacotherapy 36, (2012).; George Delgado et al., *A case series detailing the successful reversal of the effects of mifepristone using progesterone*, 33 Issues in L. & Med. 21, (2018).

that administering progesterone (or any other medical intervention) may "reverse," "cease," or "avoid" the effects of mifepristone taken as part of a medication abortion, and thus are the only apparent basis in the medical literature for the mandated information in the Act.

47. Based on this understanding, in my opinion (along with the determination of major medical associations like ACOG), there is no credible evidence to support the statements, as mandated by the Act, that a medication abortion can be "reversed," "ceased," or "avoided" by any medical intervention. Moreover, I believe that compelling physicians to communicate to their patients that abortion reversal may be possible will lead patients to falsely believe that there is an established treatment to achieve that result.

48. The Davenport and Delgado papers are self-described as "case series."[11] A case series is a report on the treatment or outcomes of a group of individual patients. Essentially, they are observational reports lacking rigorous scientific design.

49. Case studies do not constitute reliable evidence of the safety or effectiveness of an experimental or novel medical treatment. To the contrary, they constitute the lowest form of research evidence available[12] because they are "often biased by the author's experience or opinions and there is no control of confounding factors."[13] Case series are particularly vulnerable to selection bias, which means the results reported may not appropriately represent the wider population.

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[11] *Id.*

[12] Deborah J. Cook et al., *Rules of evidence and clinical recommendations on the use of antithrombotic agents*, 102 (4 Suppl.) Chest, 305S, (1992).

[13] Patricia B. Burns, Rod J. Rohrich & Kevin C. Chung, *The Levels of Evidence and their role in Evidence-Based Medicine,* 128 Plastic and Reconstructive Surgery 305, (July 2011).

50. Unlike randomized clinical trials, case studies do not include a control group. The control group provides a benchmark to help determine whether the medical intervention in question results in a different outcome than providing no medical intervention at all. If the intervention results in outcomes similar to the benchmark rate in the control group, then there is no evidence that the intervention is effective. The Delgado and Davenport series included no control group, meaning they did not collect data on patients who did *not* receive progesterone treatment after taking mifepristone.

51. The only other reliable means by which to determine the efficacy of a novel or experimental treatment is when the outcome of a situation without medical intervention is understood to a very high degree of certainty. For example, if there is a medical condition from which, historically, virtually all patients die without exception, then one may be able to measure the efficacy of a novel intervention against that benchmark.

52. Without a clear comparison group,[14] the Delgado and Davenport case studies lack a reliable benchmark against which to determine whether their proposed intervention—administration of progesterone—is effective. Without such a benchmark, there is simply no way to reliably determine whether so-called "reversal" treatment has any effect, particularly where the medical literature has documented significant rates of continuing pregnancy after taking

[14] Grossman and White note that there is only a single published report to examine the rates of continuing pregnancy after a 200-mg dose of mifepristone, "which is the dose most commonly used in current medication-abortion regimens," and that this report concerned only 30 women all of whose pregnancies were at or less than 7 weeks' gestation. *Abortion "Reversal"—Legislating without Evidence, supra* note 13. Grossman and White further note that "there are no published data on rates of pregnancy continuation after a 200-mg dose of mifepristone alone at more than 7 weeks' gestation" and thus, no benchmarks at all against which to measure the efficacy of "reversal" regimens at this stage of pregnancy. *Id.*

mifepristone alone.[15] Indeed, Delgado and Davenport admit that the ongoing pregnancies documented in their case study "may have survived without progesterone therapy."[16]

53. To answer the question of whether high-dose progesterone increases the chances that a pregnancy will continue after a woman receives mifepristone, one would have to design a prospective trial that specifies the research question to be asked or hypothesis to be tested, defines the eligibility criteria for women to participate, describes the treatment regimen to be administered as well as the comparison group, specifies the data (including outcome data) to be collected, and ensures rigorous quality control mechanisms for data collection. Ideally, one would design a randomized trial that gave half the women progesterone and half the women a placebo, then compare pregnancy continuation rates between these two groups. Such a design, and only such a design, would allow for a strong claim that administration of progesterone increases the chances of a continued pregnancy.

54. I am aware that the only controlled double-blind clinical trial of this sort designed to test the hypothesis that the effects of mifepristone can be "reversed" via progesterone was halted before its completion due to serious safety concerns.[17] Three of twelve patients who had begun participation in the trials (*i.e.*, who had taken mifepristone, had taken either progesterone or a placebo, and had not taken misoprostol within the timeframe prescribed in the usual course of a medication abortion) experienced severe hemorrhage requiring hospital transport.[18] One patient required a blood transfusion.[19]

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[15] *Abortion "Reversal"—Legislating without Evidence, supra* note 13; *A case series detailing the successful reversal of the effects of mifepristone using progesterone, supra* note 14.
[16] *Id.* at 29.
[17] Mitchell D. Creinin et al., *Mifepristone Antagonization with Progesterone to Prevent Medication Abortion: A randomized controlled trial*, 135 Obstetrics &Gynecology 158, (January 2020).
[18] *Id.*
[19] *Id.*

55. This study was cited by the ACOG/SFP guidelines in support of their statement that "limited available evidence suggest that use of mifepristone alone without subsequent administration of misoprostol may be associated with an increased risk of hemorrhage."[20]

56. Because I am not an OBGYN, I am not offering any opinion as to the biological possibility or plausibility of medication abortion "reversal" via progesterone, nor on its likely safety. Rather, it is my opinion that there is not reliable evidence from human clinical trials demonstrating that the effects of mifepristone taken as part of a medication abortion can be safely or effectively "reversed" (or "avoided" or "ceased") by administration of progesterone. It is further my opinion that it is therefore unethical for physicians or other medical professionals to be forced to inform patients seeking a medication abortion that "it may be possible to avoid, cease, or even reverse the intended effects of a chemical abortion utilizing mifepristone if the second pill has not been taken."

The Papers Claiming to Support the Efficacy of "Reversal" Treatments May Be Based on Unethical Research

57. The Delgado and Davenport papers raise ethical concerns about whether proper protocols were followed for conducting research on human subjects. In my opinion, the activities described in the 2012 and 2018 paper constitute research on human subjects as it is commonly understood and as it is defined by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in its *Belmont Report:* "an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge."[9]

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[20] ACOG, *supra* note 12.

58. Media reports that I have read suggest that the 2012 Delgado and Davenport paper did not obtain Institutional Review Board ("IRB") approval.[21] Media reports similarly suggest that for the 2018 paper Delgado and Davenport obtained IRB approval to conduct only retroactive analysis—i.e., looking at data from treatment that had already occurred—but never obtained IRB approval to collect prospective data or provide experimental treatment for the purpose of conducting research on human subjects.[22]

59. The professional norm and expectation in the biomedical research community is that research on human subjects should be approved by an IRB. Generally, before approving research proposals, IRBs are necessary to determine that (1) risks to subjects will be minimized through sound research design and, whenever appropriate, the use of procedures already being performed on subjects for clinical purposes; (2) risks will be "reasonable in relation to" the anticipated benefits for the subjects and to the importance of any discoveries that are expected to result; (3) selection of subjects will be equitable, taking special consideration of research involving vulnerable populations, including pregnant women; (4) informed consent will be sought; (5)

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[21] Shannon Firth, *Reversing Abortion Pill: Can It Be Done?, MedPage Today* (Feb. 24, 2015), http://www.medpagetoday.com/0BGYN/General0BGYN/50164 ("In an email, Delgado said that... institutional review board is not required to follow cases").; Paul Sisson, *Doctor began abortion reversal movement,* The San Diego Union-Tribune (Apr. 11, 2015), http://www.utsandiego.com/news/2015/apr/11 /george-delgado-abortion-reversal/?#article-copy ("Delgado said his nonprofit organization . . . which runs the Abortion Pill Reversal Program—has not begun working with a review board . . . . ").

[22] Azeen, Ghorayshi, *A Study About the "Abortion Reversal" Procedure Was Just Withdrawn For Ethical Issues*, Buzzfeed News (July 17, 2018), https://www.buzzfeednews.com/article/azeenghorayshi/abortion-pill-reversal-study-withdrawn ("The University of San Diego asked for the paper to be withdrawn, spokesperson Pamela Payton told Buzzfeed News, because it had 'ambiguous' wording regarding the university's ethics board, 'leading many readers to incorrectly conclude that the [school] reviewed and approved the entire study," when "in reality . . . the ethics board only approved analyzing preexisting data, not collecting it."); *see also Abortion "Reversal"—Legislating without Evidence, supra* note 13; *A case series detailing the successful reversal of the effects of mifepristone using progesterone, supra* note 14, at 1492.

consent will be appropriately documented; (6) the research proposal provides for monitoring the collected data to ensure subject safety; and (7) the study will follow appropriate efforts to protect subjects' privacy and maintain the confidentiality of data.[23] Specifically, IRBs must review and approve research protocols, informed consent documents, recruitment materials and other core study documents before participants are enrolled in the research.

60. Without IRB approval, there are serious questions about the reliability of any data a physician purports to have collected regarding the efficacy and safety of a proposed treatment, as well as whether the research was conducted ethically.

61. I have participated as a researcher in clinical trials and research studies involving human subjects. Every trial or study in which I have participated has been through the IRB approval process prior to the initiation of the research. This is done not only because it is the professional norm (and for this reason every institution I have worked for has required this) and because it is ethical, but also because if the research demonstrates that a new course of treatment is safe and effective, we want the medical community to know that the research was done rigorously and that the results are valid—in other words, that the treatment is evidence-based—so that other physicians can offer to recommend the treatment to their patients with confidence. IRB approval is also important to assuring other physicians that the research results were obtained ethically.

62. Indeed, in their 2012 paper, Delgado and Davenport indicated that they, too, considered the progesterone "reversal" protocol to be experimental and in need of clinical trials to demonstrate its safety and efficacy ("We welcome further clinical trials utilizing this protocol or others. . . We believe that *if* further trials confirm the success without complications of this or

[23] *See* Code of Federal Regulations, 45 U.S.C. § 46.111.

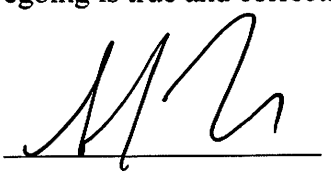
similar protocols, it should become the standard of care for obstetrician-gynecologists, family physicians, and emergency department physicians to attempt mifepristone reversal on patient request.")[24] (Emphasis added.) Thus their subsequent use of a range of unspecified progesterone "reversal" protocols in hundreds of women, outside of a formal IRB-approved protocol, is difficult to understand.

Conclusion

63. For all of these reasons, it is my opinion that the requirements of the Act are contrary to medical ethics and undermine informed consent, resulting in potential harm to patients, physicians, and the integrity of the medical profession. Rather than ensuring patients are firm in their decision to seek an abortion, the Act increases the chances that patients will begin medication abortions before they are sure that doing so is the right decision for them, under the mistaken belief that the abortion can be "reversed" once it has begun. Instead of providing patients with relevant information, the Act forces physicians to mislead patients and encourage them to undertake an entirely unproven treatment, the safety and effectiveness of which has not been reliably demonstrated.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: August 29, 2020



Steven Joffe, M.D., M.P.H.

[24] Delgado, *supra* note 10 (emphasis added).

EXHIBIT A

UNIVERSITY OF PENNSYLVANIA - PERELMAN SCHOOL OF MEDICINE
Curriculum Vitae

Date: 08/07/2020

Steven Joffe, MD, MPH

If you are not a U.S. citizen or holder of a permanent visa, please indicate the type of visa you have:
none (U.S. citizen)

Education:

1988	A.B.	Harvard College (Fine Art)
1992	M.D.	University of California, San Francisco School of Medicine (Medicine)
1996	M.P.H.	University of California, Berkeley (Epidemiology)

Postgraduate Training and Fellowship Appointments:

1992-1993	Intern, Pediatrics, University of California, San Francisco
1993-1995	Resident, Pediatrics, University of California, San Francisco
1996-1997	Research Fellow, Department of Research, Kaiser Permanente Northern California
1997-2000	Clinical Fellow, Pediatric Hematology/Oncology, Children's Hospital Boston and Dana-Farber Cancer Institute
1998-2000	Research Fellow, Clinical Effectiveness, Children's Hospital Boston
1998-2000	Fellow, Medical Ethics, Harvard Medical School
2000-2001	Faculty Fellow, Professional Ethics, Center for Ethics and the Professions, Harvard University

Military Service:

[none]

Faculty Appointments:

2000-2004	Instructor of Pediatrics, Harvard Medical School
2004-2010	Assistant Professor of Pediatrics, Harvard Medical School
2010-2013	Associate Professor of Pediatrics, Harvard Medical School
2012-2013	Associate Professor of Global Health and Social Medicine (Secondary), Harvard Medical School
2013-2016	Associate Professor of Medical Ethics and Health Policy, University of Pennsylvania School of Medicine
2013-2017	Associate Professor of Medical Ethics and Health Policy in Pediatrics, University of Pennsylvania School of Medicine (Secondary)
2016-2017	Emanuel and Robert Hart Associate Professor in Bioethics, University of Pennsylvania School of Medicine
2017-2018	Emanuel and Robert Hart Professor in Bioethics, University of Pennsylvania School of Medicine

2017-present	Professor of Medical Ethics and Health Policy in Pediatrics, University of Pennsylvania School of Medicine (Secondary)
2018-present	Founders Professor of Medical Ethics and Health Policy, University of Pennsylvania School of Medicine

Hospital and/or Administrative Appointments:

1995-1997	Assistant Physician, Department of Pediatrics, University of California, San Francisco
1995-1997	Medical Staff, Department of Pediatrics, St. Luke's Hospital, San Francisco, CA
1995-1997	Pool Physician, Department of Pediatrics, Kaiser Permanente, Walnut Creek, CA
1998-2002	Medical Staff, Department of Pediatrics, Saints Memorial Medical Center, Boston, MA
1998-2010	Medical Staff, Department of Pediatrics, Newton-Wellesley Hospital, Newton, MA
2000-2013	Attending Physician, Department of Medicine Division of Hematology and Oncology, Children's Hospital Boston
2000-2013	Attending Physician, Department of Pediatric Oncology, Dana-Farber Cancer Institute
2000-2013	Medical Staff, Department of Pediatrics, Winchester Hospital, Winchester, MA
2001-2013	Hospital Ethicist, Dana-Farber Cancer Institute
2007-2013	Faculty Director, Survey and Data Management Core, Dana-Farber Cancer Institute
2011-2013	Director, Ethics Program in Clinical and Translational Research (EPiCTR), Harvard Catalyst (Associate Director, 2008-2011), Harvard Medical School
2013-present	Director, Penn Fellowship in Advanced Medical Ethics, Perelman School of Medicine
2013-2019	Attending Physician, Hematopoietic Stem Cell Transplantation, Children's Hospital of Philadelphia
2014-present	Chief, Division of Medical Ethics, Department of Medical Ethics and Health Policy, University of Pennsylvania Perelman School of Medicine
2017-present	Director, Postdoctoral T32 Training Program in the Ethical, Legal and Social Implications (ELSI) of Genetics and Genomics, University of Pennsylvania Perelman School of Medicine
2019-present	Interim Chair, Department of Medical Ethics and Health Policy, Perelman School of Medicine

Other Appointments:

2013-present	Member, Abramson Cancer Center
2016-present	Senior Fellow, Leonard Davis Institute
2017-present	Senior Fellow, Penn Center for Precision Medicine

2019-present	Co-Director, Cancer Control Program, Abramson Cancer Center

Specialty Certification:

1995	American Board of Pediatrics (1995-2019)
2000	American Board of Pediatrics, Hematology/Oncology Sub-Board (2000-2019)

Licensure:

1993-1997	California License Registration
1997-2013	Massachusetts License Registration
2013	Pennsylvania License Registration

Awards, Honors and Membership in Honorary Societies:

1983	National Merit Scholarship
1985-1988	John Harvard Scholar, Harvard College
1987	Phi Beta Kappa, Harvard College
1988	Regents Scholar, University of California, San Francisco
1992	Academic Excellence Award (Co-Valedictorian), University of California, San Francisco
1992	Alpha Omega Alpha, University of California, San Francisco
1995	Housestaff Teaching Award, Department of Pediatrics, University of California, San Francisco
2002	Award for Excellence in Human Research Protection, Health Improvement Institute
2008	Elected member, Society for Pediatric Research
2011	Excellence in Tutoring Award, Harvard Medical School
2012	Elected member, American Pediatric Society
2013	Fellow, The Hastings Center

Memberships in Professional and Scientific Societies and Other Professional Activities:

International:

2019	External Review Committee, Biomedical Ethics Unit, McGill University School of Medicine, Montreal, Canada

National:

1992-2000	American Academy of Pediatrics
1999-Present	American Society of Clinical Oncology (Member, Subcommittee on Genetic Testing 2001-2003 Member, Ethics Committee 2002-2006 and 2017-9 Member, Data Governance Oversight Committee, CancerLinQ, 2014-2015)
2001-Present	American Society of Bioethics and Humanities
2003-Present	Children's Oncology Group, Bioethics Committee (Vice-Chair 2003-2008

	Chair 2008-2017)
2003-Present	Public Responsibility in Medicine and Research (PRIM&R) (Member, Annual Conference Planning Committee 2006-2009 Member, Education Committee 2007-2010)
2005-2011	Cancer and Leukemia Group B, Ethics Committee
2006-2007	National Institutes of Health, National Cancer Institute Central IRB Evaluation Review Panel
2007-Present	U.S. Food and Drug Administration, Pediatric Ethics Subcommittee, Advisory Committee
2008-Present	American Society for Blood and Marrow Transplantation
2008-2012	Genzyme Corporation (Data Monitoring Committee Member)
2008	National Institutes of Health, Center for Scientific Review, Ad hoc member, Special Emphasis Panel (ZRG1 HOP-J(90)S)
2009-2020	Center for International Blood and Marrow Transplantation Research, Health Policy Working Committee (Co-chair 2009-2014)
2009	National Cancer Institute/American Society of Clinical Oncology, Planning Committee, Science of Clinical Trial Accrual Symposium
2009	National Institutes of Health, Biobehavioral and Behavioral Processes IRG, Division of AIDS, Behavioral and Population Sciences, Center for Scientific Review, Ad Hoc Member, Challenge Grant Review Panel Member (Stage 1)
2009	National Institutes of Health, National Human Genome Research Institute (Ethical, Legal and Social Implications Program), Ad Hoc Member, Challenge Grant Review Panel Member (Stage 1)
2010-2013	U.S. Department of Health and Human Services, Secretary's Advisory Committee for Human Research Protections (SACHRP)
2011-2016	NHGRI Clinical Sequencing Exploratory Research (CSER) Consortium ELSI Group (Chair 2013-6)
2011	National Institutes of Health Clinical Center, Board of Scientific Counselors, Ad Hoc Member for Review of the Department of Bioethics
2013-2016	National Institute of Allergy and Infectious Diseases, National Institute of Allergy and Infectious Diseases (NIAID) HIV Prevention Data and Safety Monitoring Board

	- Africa
2014-2020	Advisory and Executive Committees, Center for International Blood and Marrow Transplant Research (CIBMTR)
2014-2018	African HIV Data Safety and Monitoring Board, National Institute of Allergies and Infectious Diseases (NIAID), Division of AIDS (DAIDS)
2014-Present	American Society of Human Genetics
2015-Present	Board of Scientific Counselors, National Institutes of Health Clinical Center
2015-Present	Children's Oncology Group Pediatric MATCH Clinical Trial (Co-chair, Germline Subcommittee)
2015-2016	Committee on Federal Research Regulations and Reporting Requirements, National Academy of Sciences
2015	National Institutes of Health Clinical Center, Board of Scientific Counselors, Ad Hoc Member for Review of the Department of Bioethics
2017-Present	Genomics and Society Working Group, National Human Genome Research Institute, NIH (Chair, 2020-)
2018	Member, Advisory Committee to the NIH Director, Working Group on Ethical Considerations for Industry Partnership on Research
2018	National Institutes of Health Study Section ZHG1 HGR-P (M2) 1 for review of H3Africa ELSI proposals
2019-Present	American Society for Preventive Oncology
2019-Present	Disclosure Symposium Working Group on Relevancy, Association of American Medical Colleges
2019-Present	Helping End Addictions Long-Term Partnership Committee, National Institutes of Health
2019-Present	Multi-Regional Clinical Trials Center, Harvard University (Co-chair, "Promoting Global Clinical Research in Children, 2019-)
2020-Present	Cure Sickle Cell Initiative, National Heart Lung and Blood Institute (Member, External Scientific Panel, 2020-)
2020	National Human Genome Research Institute (Ad hoc member, GNOM-G 2 Study Section)

Local:

2008-2011	Department of Public Health, Commonwealth of Massachusetts, Altered Standards of Care Advisory Committee
2012-2013	Massachusetts General Hospital, Advisory Committee, Program in Cancer Outcomes Research Training (PCORT), Institute for Technology Assessment
2020	Member, Advisory Committee on Ethical Allocation Framework for Emerging Treatments of COVID-19, Pennsylvania Department of Health

Editorial Positions:

2005-2009	Editorial Board Member, Critical Reviews of Oncology and Hematology
2005-2013	Editorial Board Member, Journal of Clinical Oncology
2013-present	Peer reviewer, Genetics in Medicine
2014-present	Peer reviewer, Clinical Trials
2014-present	Peer reviewer, Pediatrics
2014-present	Peer reviewer, PLoS One
2014-present	Peer reviewer, Journal of Clinical Oncology
2014-present	Peer reviewer, PLoS Medicine
2014-present	Peer reviewer, Lancet
2014-present	Peer reviewer, Pediatric Blood and Cancer
2014-present	Peer reviewer, JAMA
2014-present	Peer reviewer, Hastings Center Review
2014-present	Peer reviewer, JAMA Pediatrics
2015-Present	Peer Reviewer, Generating Evidence & Methods to Improve Patient Outcomes
2015-present	Peer reviewer, American Journal of Bioethics-Empirical Bioethics
2015-Present	Peer Reviewer, JAMA Internal Medicine
2015-present	Peer reviewer, New England Journal of Medicine
2015-present	Peer reviewer, Journal of the National Cancer Institute
2015-present	Peer reviewer, BMC Medical Ethics
2016-Present	Peer Reviewer, Journal of Law and the Biosciences
2016-Present	Peer reviewer, Journal of Empirical Research on Human Research Ethics
2016-Present	Peer Reviewer, Journal of Pediatrics
2016-Present	Peer Reviewer, American Journal of Bioethics
2016	Peer reviewer, National Academy of Sciences/National Academy of Medicine
2016-Present	Peer Reviewer, Journal of Medical Ethics
2017-Present	Peer Reviewer, Journal of Oncology Practice
2019-Present	Editorial Board member, American Journal of Bioethics
2019-Present	Editorial Board Member, Ethics and Human Research

Academic and Institutional Committees:

1998-2012	Member, Institutional Review Board, Dana-Farber Cancer Institute
2000-2013	Member, Ethics Advisory Committee, Children's Hospital Boston
2000-2013	Member, Ethics Advisory Committee, Dana-Farber Cancer Institute (Co-chair 2001-2009)
2000-2009	Member, Board of Trustees Quality Assurance and Risk Management Committee, Dana-Farber Cancer Institute
2001-2004	Member, Research Integrity and Compliance Committee, Dana-Farber Cancer Institute
2001-2012	Member, Clinical Research Leadership Committee (formerly Clinical Research Policy and Operations Committee), Dana-Farber/Harvard Cancer Center
2002-2013	Member, Steering Committee, Division of Medical Ethics, Harvard Medical School
2003	Member, Organizational Ethics Task Force on the Refusal of Blood Products, Children's Hospital Boston
2003-2009	Partners HealthCare, Ethics Leaders Committee
2004-2013	Partners HealthCare, Embryonic Stem Cell Research Oversight (ESCRO) Committee
2005-2009	Member, Ethics Leaders, Harvard Medical School
2005-2006	Partners HealthCare, Tissue Banking Task Force
2008-2010	Member, Admissions Committee, Harvard Medical School
2009-2013	Member, Informed Cohort Oversight Board, Boston Children's Hospital
2011-2013	Expert Reader and Examiner, Committee on Awards and Honors, Harvard Medical School
2012-2013	Member, Research Conflict of Interest Management Committee, Dana-Farber Cancer Institute
2013-2015	Member, Internal Review Committee, Master of Science in Health Policy program, PSOM
2013-2019	Member, Ethics Committee, Children's Hospital of Philadelphia
2015-2016	Member, Committee on Teaching-Part 2, Perelman School of Medicine
2017-Present	Steering Committee member, Community Engagement and Research Core, University of Pennsylvania
2017	Member, Public Health Strategic Planning Subcommittee, Perelman School of Medicine
2017-present	Member, Committee on Appointments and Promotions (on leave 2019-21)
2017-2019	Member, Pediatric Patient-Reported Symptom Tracking in Oncology quality improvement project, Children's Hospital of Philadelphia
2018-2020	Member, Committee on Academic Freedom and Responsibility, Perelman School of Medicine
2018-Present	Member, Clinical Information Systems Genomics Oversight Committee, Penn Medicine

2018	Member, Internal Review Committee, Department of Biostatistics, Epidemiology, and Informatics
2019-Present	Member, Operating Committee, Abramson Cancer Research Career Enhancement and Related Activities Core
2020	Member, Internal Review Committee, Department of Genetics, PSOM
2020-Present	Member, Conflict of Interest Committee, Perelman School of Medicine
2020-Present	Member, COVID Clinical Trials Working Group
2020-Present	Member, COVID 19 Clinical and Translational Research Oversight Committee

Major Academic and Clinical Teaching Responsibilities:

2000-2003	Attending Physician, Pediatric Oncology, Jimmy Fund Clinic, Dana-Farber Cancer Institute (4 Fellows for 100 hours every year)
2000-2002	Attending Physician for Inpatient Oncology Service, Children's Hospital Boston (6 Fellows and 4 Residents for 200 hours every year)
2002-2013	Attending Physician for Hematopoietic Stem Cell Transplant Service, Children's Hospital Boston (6 Fellows and 2 Residents for 150 hours every year)
2003-2012	Attending Physician, Pediatric Stem Cell Transplant Outpatient Service, Dana-Farber Cancer Institute (3-4 Fellows for 200 hours every year)
2003	Informed Consent Presentation, Breast Cancer: Current Controversies and New Horizons, Harvard Medical School (CME)
2003-2011	Case-Based Ethical Dilemmas, Practical Aspects of Palliative Care, Harvard Medical School (CME Single Presentation every year)
2008-2012	Medical Ethics and Professionalism Course for first-year medical students (one 2 hour session per week for 14 weeks)
2008	"Therapeutic Innovation or Research" - Seminar, June 2008, Harvard School of Public Health
2008	"Ethics of research with human subjects" - Seminar, June 2008, Harvard Medical School
2008	"Informed consent to treatment and research" - Seminar, October 2008, Division of Medical Ethics, Harvard Medical School
2009	"The ethical conundrum of incidental findings in clinical & translational research" - Lecture, June 2009, Harvard Catalyst Colloquium Series
2009	"Informed consent to treatment and research" - Seminar, September 2009, Division of Medical Ethics, Harvard Medical School
2009	"Conflict of Interest in Biomedical Research" - Seminar, October 2009, Longitudinal Clinical Research Seminar/Bioethics Module, ME 731.0a, Scholars in Clinical Science Program, Harvard Medical School
2009	"Ethics and professional integrity in clinical and translational

	research" - Seminar, October 2009, Clinical Investigator Training Program, Harvard Medical School
2009	"At the point of the spear: ethical and scientific challenges in translational trials" - Lecturer, November 2009, Introduction to Clinical Investigation Course, Harvard Catalyst
2010	"Cancer patients' attitudes towards stored tissue research: outcomes and value of a factorial survey" - Lecture, January 2010, Harvard Pediatric Health Services Research Fellowship Program
2010	"Ethics in clinical research" - March 2010, Department of Medicine Residency Program, Children's Hospital Boston
2010	"What makes clinical research ethical?" - March 2010, Introduction to Clinical Investigation Course, Harvard Catalyst
2010	"The scientist as a responsible member of society" - June 2010, Responsible Conduct of Research Course, Dana-Farber Cancer Institute
2010	"Innovative treatment - research" - June 2010, Harvard Medical School Bioethics Course
2010	"Ethical issues in medical research" - Lecture, July 2010, CURE Summer Program, Dana-Farber Cancer Institute
2010	"Ethics in medical research" - Lecture, July 2010, Harvard Catalyst Visiting Research Internship Program and Summer Clinical and Translational Research Program, Harvard Medical School
2010	"Informed consent, subject selection and recruitment" - Lecture, September 2010, Scholars in Clinical Science Program, Harvard Medical School
2010	"Ethics and integrity in clinical research" - Lecture, September 2010, Introduction to Clinical Research Course, Children's Hospital Boston
2010	"Conflicts of interest" - Lecture, October 2010, Scholars in Clinical Science, Harvard Medical School
2010	"Case-based ethical dilemmas" - Lecture, October 2010, Practical Aspects of Palliative Care Course, Harvard Medical School
2010	"Informed consent to treatment and research" - Lecture, October 2010, Harvard Medical School Ethics Fellowship, Harvard Medical School
2010	"Attitudes of cancer patients and parents toward biobanking for future research" - Lecture, November 2010, Brigham and Women's Center for Bioethics, Research in Progress Seminar
2011	"Ethical conduct of research: Issues in consent" - Lecture, January 2011, Harvard Medical School Fellowship Programs in General Medicine and Primary Care, Pediatric Health Services Research, and Complementary and Alternative Medicine, Serving the Underserved: The Responsible Conduct of Research for the Underserved
2011	"Evaluating the ethics of clinical research" - Lecture, March 2011, Introduction to Clinical Investigation Course, Harvard Catalyst
2011	"Informed consent to research" - Lecture, April 2011, Training

	Session for Department of Biostatistics and Computational Biology, Dana-Farber Cancer Institute
2011	"Ethics in medical research" - Lecture, August 2011, Visiting Research Internship Program and Summer Clinical and Translational Research Program, Harvard Catalyst
2011	"Human subjects protection in survey research" - Seminar, September 2011, UMass Boston/Dana-Farber Harvard Cancer Center Survey and Statistical Methods Core Seminar Series
2011	"Ethics in integrity in clinical research" - Lecture, September 2011, Introduction to Clinical Research Course, Children's Hospital Boston
2011	"Case-based dilemmas: Ethical challenges in end-of-life care" - Lecture, September 2011, Practical Aspects of Palliative Care Course, Harvard Medical School
2011	"Informed consent, subject selection and recruitment" - Lecture, September 2011, Scholars in Clinical Science Program, Harvard Medical School
2011	"Conflicts of interest" - Lecture, September 2011, Scholars in Clinical Science Program, Harvard Medical School
2011	"Informed consent to treatment and research" - Lecture, October 2011, Ethics Fellowship, Harvard Medical School
2011	"Ethics in clinic research" - Lecture, October 2011, Clinical Investigator Seminar, Dana-Farber Cancer Institute
2012	"Children's capacity to participate in research decisions" - Lecture, January 2012, Department of Medicine Grand Rounds, Children's Hospital Boston
2012	"Ethics & professional integrity in clinical and translational research" - Lecture, January 2012, Clinical Investigator Training Program, Harvard Medical School
2012	"The scientist as a responsible member of society" - Lecture, March 2012, Responsible Conduct of Research Course, Dana-Farber Cancer Institute
2012	"Responsible conduct of research" - Lecture, May 2012, Pediatric Health Services Research Fellowship, Children's Hospital Boston
2012	"Ethics in medical research" - Lecture, July 2012, Visiting Research Internship Program and Summer Clinical and Translational Research Program, Harvard Catalyst/HMS
2012	"Informed consent, subject selection and recruitment" - Lecture, September 2012, Scholars in Clinical Science Program, Harvard Catalyst/HMS
2012	"Ethics and integrity in clinical research" - Lecture, September 2012, Introduction to Clinical Research Course, Children's Hospital Boston
2012	"Conflict of interest" - Lecture, September 2012, Scholars in Clinical Science Program, Harvard Catalyst/HMS
2012	"Informed consent to treatment and research" - Lecture, October

	2012, Ethics Fellowship, Harvard Medical School
2013	"Evaluating the Ethics of Clinical & Translational Research" - Lecture, October 2013, Pediatric Translational Research Workshop for Basic Scientists, Children's Hospital of Philadelphia
2013	"Ethics in Biomedical Research," Guest Lecture, Health Policy and Research Methods I
2013	Course Director, BIOE701, "Bioethics Proseminar"
2013-Present	BIOE701/702, "Bioethics Proseminar," Course Director and Instructor. Two-semester course for postdoctoral fellows given annually.
2014	"Evaluating Informed Consent for Clinical Research" - Lecture, EPI690, University of Pennsylvania
2014	"Mandate or Millstone? The Ethical Challenge of Genomic Incidental Findings," Ellen Hyman-Browne Memorial Lecture, October 2014, Children's Hospital of Philadelphia
2014	"Evaluating the Ethics of Clinical Research" - How to Be An Academic Radiologist, Department of Radiology, University of Pennsylvania Perelman School of Medicine
2014	"Ebola virus disease" - GlobalMed, November 2014, University of Pennsylvania
2014	"Ethics in Biomedical Research" - Guest lecture, Health Services and Policy Research Methods I, December 2014, University of Pennsylvania
2014-2016	Faculty mentor to Elliott Weiss, MD, Postdoctoral Fellow in Bioethics and Neonatology Fellow
2014-2016	Faculty mentor to Erin Aakhus, MD, Fellow in Hematology/Oncology
2014	Capstone project mentor to Divya Yerramilli, MD/MBE student
2014	"Can we use children in research for the benefit of others?" Bioethics Boot Camp lecture & discussion, Department of Medical Ethics and Health Policy, PSOM
2015	"Pediatric Ethics" - Lecture, MOD610 Introduction to Medical Ethics, February 2015, University of Pennsylvania
2015	"History of Research Ethics" and "Pediatric Ethics" - Leader, Small group discussions, MOD610 Introduction to Medical Ethics, February 2015, University of Pennsylvania
2015	"Ethics in pediatric hematopoietic stem cell transplant," Pediatric HSCT Education Series, Children's Hospital of Philadelphia
2015	"Involving Children in Decisions about Research"- Pediatric Grand Rounds, Children's Hospital of Philadelphia, April 2015
2015	"Ethics in Biomedical Research," Guest lecture, Health Services and Policy Research Methods I
2016	"Responsibilities of Principal Investigators in Multicenter Clinical Trials," 1.5 hour lecture to Dept Colloquium, History & Sociology of Science

2016	Small group facilitator, FR601, "Bioethics and Professionalism"
2016	"Adaptive clinical trial designs: an ethical perspective," Current Issues Regarding the Use of Adaptive Designs in Clinical Trials conference, Center for Clinical Epidemiology and Biostatistics
2016	"Can we use children in research for the benefit of others?" Bioethics Boot Camp, Department of Medical Ethics and Health Policy, PSOM
2016	External Reviewer, proposed Master of Science in Methods in Medical Ethics Degree Program, University of Oxford
2016-2018	Faculty mentor to Bege Dauda, PhD, Postdoctoral Fellow in Advanced Biomedical Ethics
2016	"Ethics in Biomedical Research," HPR603 lecture
2016	BIOE556, "Empirical Approaches to Medical Ethics and Health Policy," Instructor and Course Director
2016-2017	Faculty mentor to Justin Clapp, PhD, Postdoctoral Fellow, Anesthesia
2016	BIOE 560, "Pediatric Ethics." Co-instructor and co-course director.
2017	Ob/Gyn Grand Rounds, "Ethical and Policy Challenges in Research with Biospecimens," Lecturer
2017	Population Science Seminar, Responsibilities of Principal Investigators in Multicenter Clinical Trials, Abramson Cancer Center. January 26
2017	"Ethics in pediatric hematopoietic stem cell transplantation," lecture, pediatric HSCT program, CHOP
2017	Bioethics Bootcamp lecture: Can we use children in research for the benefit of others?
2017-Present	Faculty mentor to Kaitlyn Leahey, Student, Master of Science in Medical Ethics
2017	Faculty mentor to Katherine Saylor, PhD Student, University of North Carolina at Chapel Hill (Visiting student, UPenn, summer 2017)
2017	Faculty Mentor to Saad Shamshair, MD student, University of Maryland; Visiting student, UPenn, Summer 2017
2017	"Ethics in Biomedical Research," HPR603 lecture
2018	"Attitudes towards return of results among participants in the Jackson and Framingham Heart Studies," Basser Center for BRCA
2018	"Responsibilities of principal investigators in multicenter clinical trials," Leonard Davis Institute/Division of General Medicine Seminar
2018	Journal Club, Department of Genetics
2018	"Ethics in Pediatric Stem Cell Transplantation," lecture in Advances in Cellular Immunotherapy and Stem Cell Transplantation Symposium, Children's Hospital of Philadelphia
2018	Lecturer, "Ethics in pediatric hematopoietic cell transplantation," pediatric hematopoietic stem cell program, CHOP
2018	"Ethics In Biomedical Research," lecture, Health Services and

	Policy Methods I
2018	BIOE 560, "Pediatric Ethics." Co-instructor and co-course director.
2018-2019	Faculty capstone mentor to Timothy Lucas, MD, Master of Healthcare Innovation student
2019	BIOE 603, "Clinical Ethics." Course co-instructor and co-director.
2019	FR601, Bioethics and Professionalism, Small Group Facilitator
2019	"Ethics and Innovative Trial Design," Lecture, Research Ethics & Policy Series, PSOM
2019	"Ethics in Medicine," Future Women in Health Club, College of Liberal & Professional Studies, University of Pennsylvania
2019	Capstone adviser to Master of Bioethics candidate Donna Snyder, MD
2019	Instructor, HCIN-612, Ethics of Health Care Innovation Research (Online Master of Health Care Innovation Research)
2019	"Ethics In Biomedical Research," lecture, Health Services and Policy Methods I

Lectures by Invitation (Last 5 years):

Jan, 2015	"Nonfinancial Incentives to Research Participants" - Petrie-Flom Center for Health Law Policy, Biotechnology and Bioethics, Harvard Law School, presented at Brocher Institute, Hermance, Switzerland
Feb, 2015	"Involving Children in Important Medical Decisions" - Pediatric Ethics Grand Rounds, Visiting Scholar, Department of Pediatrics and Center for Bioethics, UNC Chapel Hill School of Medicine
Mar, 2015	"The Patient-Doctor Relationship" - Department of Bioethics, National Institutes of Health Clinical Center
May, 2015	"Empirical Methods in Bioethics Education" - Presidential Commission for the Study of Bioethical Issues, Perelman School of Medicine, University of Pennsylvania
May, 2015	"Enrolling Patients with Cancer in Early-Phase Clinical Trials: The Ethical Perspective" - ASCO Annual Meeting, Chicago, IL
Sep, 2015	"Integrating sequencing into cancer care: perspectives of patients and oncologists" - Individualized Medicine Conference, Mayo Clinic, Rochester, MN
Sep, 2015	"Patient-Centered Research: From Consent to Outcomes," National Human Genome Research Institute, Bethesda, MD
Oct, 2015	"Navigating the Boundary between Research and Care in Translational Genomics," American Society of Bioethics and Humanities Annual Meeting, Houston, TX
Oct, 2015	"Conflicts of Interest," National Institutes of Health Clinical Center, Bethesda, MD
Oct, 2015	"The Patient-Doctor Relationship," Department of Bioethics, National Institutes of Health Clinical Center, Bethesda, MD
Nov, 2015	"Could this happen to you? Lessons learned from the University of Minnesota." Closing General Session, Public Responsibility in

	Medicine & Research Annual Meeting, Boston, MA
Dec, 2015	"Returning Diagnostic, Uncertain and Incidental Genomic Results: Bioethical Considerations," Scientific Spotlight, American Society of Hematology Annual Meeting, Orlando, FL
Dec, 2015	"Research with Vulnerable Populations: The Dilemma of Risk," University of Minnesota, Minneapolis, MN
Feb, 2016	"Integrating sequencing into cancer care: perspectives of patients and oncologists," David Barap Brin Memorial Lecture, Johns Hopkins University School of Medicine, Baltimore, MD
Feb, 2016	"Navigating incapacity when caring for patients with cancer," Oncology Grand Rounds, Johns Hopkins University School of Medicine, Baltimore, MD
Apr, 2016	"Ethical challenges of monitoring clinical trials," Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, South Africa.
Apr, 2016	"Experimenting in extremis: research ethics during the Ebola epidemic" - Bioethics Grand Rounds, Cleveland Clinic, Cleveland, OH
Jun, 2016	"Ethical challenges in precision pediatric oncology," Coalition Against Childhood Cancer Annual Meeting, Philadelphia, PA
Jul, 2016	"A Learning Healthcare System for Precision Cancer Medicine," American Association for Cancer Research Think Tank on Genomics in Clinical Medicine, Washington, DC
Sep, 2016	"Involving Children in _Decisions about Research," Behavioral Science Committee, Children's Oncology Group, Atlanta, GA
Oct, 2016	"Quality, Evaluation, and Research: Balancing Human Protection and Knowledge Generation," Advisory Panel on Research, Association of American Medical Colleges, Washington, DC
Oct, 2016	"Opportunities and Challenges in Precision Pediatric Oncology", Cynthia Jean Stolman Memorial Lecture in Medical Ethics, Rutgers New Jersey Medical School
Nov, 2016	"Conflicts of Interest"- Ethical and Regulatory Aspects of Clinical Research, National Institutes of Health Clinical Center
Nov, 2016	"The Patient-Doctor Relationship" - Department of Bioethics, National Institutes of Health
Nov, 2016	"Is it time for Belmont 2.0?," PRIM&R Advancing Ethical Research Conference, Anaheim,CA
Nov, 2016	"Patients' and Physicians' Willingness to Participate in Pragmatic Clinical Trials," PRIM&R Advancing Ethical Research Conference, Anaheim, CA
Dec, 2016	"Seamless Cancer Drug Development: Patient Protections & Ethical Considerations," The Drug Development Paradigm in Oncology, National Cancer Policy Forum, Washington, DC
Feb, 2017	"Children's Capacity to_Make Research Decisions," Institutional Review Board Retreat, UNC-Chapel Hill,

	Chapel Hill, NC
Apr, 2017	"Responsibilities of Principal Investigators in Multicenter Clinical Trials," Ruth C. Brufsky Memorial Lecture in Medical Ethics, Dana-Farber Cancer Institute, Boston, MA
May, 2017	"Access vs. Evaluation: An Enduring Dilemma in Therapeutic Development," Keynote Speaker, Center for Clinical and Translational Research Science Day, Seattle Children's Hospital, Seattle, WA
Jun, 2017	"Attitudes towards return of results among participants in the Jackson and Framingham Heart Studies," 4th ELSI World Congress, Farmington, CT
Jun, 2017	"Building a Learning Health Care Culture: Lessons from Pediatric Oncology", Department of Pediatrics & Communicable Diseases, University of Michigan School of Medicine
Jul, 2017	"Financial Barriers to Trial Participation: Ethical Considerations," American Society of Clinical Oncology, Alexandria, VA
Oct, 2017	"Conflicts of Interest" Ethical and Regulatory Aspects of Clinical Research, National Institutes of Health Clinical Center, Bethesda, MD
Nov, 2017	"Justification, Authority, and Accountability in IRB-Investigator Correspondence," Public Responsibility in Medicine & Research (PRIM&R) annual meeting, San Antonio, TX
Nov, 2017	"The Role of Research Ethics Consultations in IRB-reviewed Research: Opportunities and Challenges" (plenary panel moderator), Public Responsibility in Medicine & Research (PRIM&R) annual meeting, San Antonio, TX
Mar, 2018	"Navigating Difficult Decisions in Pediatric Oncology," Pediatric Grand Rounds, Memorial Sloan-Kettering Cancer Center, New York, NY
Mar, 2018	"The Patient-Doctor Relationship," Department of Bioethics, National Institutes of Health Clinical Center
Apr, 2018	"Ethical issues surrounding cancer treatment," National Breast Cancer Coalition Annual Meeting, Arlington, VA
May, 2018	"Achieving the multiple aims of informed consent to research," Harvard Medical School Catalyst Research Community Forum, Keynote Address, Boston, MA
Sep, 2018	"Bedside to Bench or Bench to Bedside: The Ethics of the Investigator-Participant Relationship," National Institutes of Health, Bethesda, MD
Nov, 2018	"Ethics and Consent in the Age of Precision Medicine - Forging a Path Forward," Pediatric Oncology Group of Ontario, Toronto, Ontario, Canada
Nov, 2018	"Ethical Challenges of Cancer Predisposition Testing in Pediatrics," International Society of Paediatric Oncology (SIOP) Annual Meeting, Kyoto, Japan
Nov, 2018	"The Right to Try: The Ethics of Experimental Drugs," Temple Beth

	Sholom, Cherry Hill, NJ
Feb, 2019	"Precision Pediatric Oncology: an Ethical Perspective," Center for Research on Ethical/Legal/Social Implications of Psychiatric, Neurologic & Behavioral Genetics, Columbia University School of Physicians and Surgeons, New York, NY
Feb, 2019	"Building a Learning Health Care Culture: Lessons from Pediatric Oncology," Center for Medical Ethics & Health Policy, Baylor College of Medicine, Houston, TX
Apr, 2019	"Prospect of Direct Benefit and Challenges Incorporating the Concept into Clinical Trials," Duke Margolis Center/US Food & Drug Administration joint workshop on Prospect of Direct Benefit in Pediatric Clinical Trials, Washington, DC
Apr, 2019	"Building a Learning Health Care Culture: Lessons from Pediatric Oncology," Chidren's Research Institute, University of North Carolina Chapel Hill School of Medicine, Chapel Hill, NC
Apr, 2019	"Ethical Obligations Towards Research Subjects: Bedside to Bench or Bench to Bedside," Inaugural Parr Center for Ethics/Center for Bioethics Joint Lecture, University of North Carolina Chapel Hill, Chapel Hill, NC
Sep, 2019	"Ethical Aspects of Germline Reporting in Pediatric Trials," American Society of Pediatric Hematology and Oncology/Children's Oncology Group Joint Symposium, Atlanta, GA
Sep, 2019	"Bedside to Bench or Bench to Bedside: The Ethics of the Investigator-Participant Relationship," National Institute of Health Clinical Center, Bethesda, MD
Oct, 2019	"Navigating between FDA's expanded access programs & the federal Right-to-Try Act: a clinician's view," American Society of Bioethics & Humanities Annual Meeting, Pittsburgh, PA
Nov, 2019	"Building a learning health care culture: lessons from pediatric oncology," Christine Harrison Pediatric Grand Rounds, Hospital for Sick Children, Toronto, Ontario, Canada
Nov, 2019	"Navigating the research/quality improvement divide: a qualitative study of learning healthcare systems," Public Responsibility in Medicine & Research Annual Meeting, Boston, MA
Nov, 2019	"Bioethics Turns 50-Reflections from The Hastings Center," Plenary Panel Presentation, Public Responsibility in Medicine & Research Annual Meeting, Boston, MA
Nov, 2019	"Ethics of Gene Editing for Sickle Cell Disease," Keynote Lecture, NHGRI Cure Sickle Cell Now Annual Forum, Bethesda, MD
Dec, 2019	"Ethics, genomics, and precision medicine," Institute for Global Public Policy, Fudan University, Shanghai, China
Dec, 2019	"Ethics of biomedical innovation and research," Peking Union Medical College, Beijing, China
Mar, 2020	"Emerging Therapies in a New Era of Care," Franklin Insitute Public Lectures Series, Philadelphia, PA

Organizing Roles in Scientific Meetings:

Nov, 2008	Plenary Panel Moderator, "What is Exploitation in Research?", Public Responsibility in Medicine and Research (PRIM&R) Annual Meeting Orlando, Florida
Nov, 2009	Plenary Panel Moderator, "Ethics in Research: Who's minding the store?", Public Responsibility in Medicine and Research (PRIM&R) Annual Meeting Nashville, Tennessee
Oct, 2014	Moderator, "Compensation for Research Related Injuries: Interdisciplinary Perspectives", American Society of Bioethics & Humanities San Diego, CA
Nov, 2014	Organizer, "Write Winning Grant Proposals," Perelman School of Medicine at the University of Pennsylvania and Grant Writers' Seminars and Workshops University of Pennsylvania, Philadelphia PA
Dec, 2014	Session moderator/organizer, "Inside the Black Box: Empirical Research on IRBs," Public Responsibility in Medicine & Research (PRIM&R) Annual Meeting Baltimore, MD
Mar, 2015	Workshop Leader, "Children as Stem Cell Donors in Research" National Institutes of Health
Nov, 2015	Moderator, "Innovations in Subject Perspectives: Risks, Benefits, and Incidental Findings" Scientific Session, Public Responsibility in Medicine & Research Annual Meeting Boston, MA
Apr, 2019	Member, Organizing Committee, Duke Margolis Center/US Food & Drug Administration joint workshop, "Prospect of Direct Benefit in Pediatric Clinical Trials" Washington, DC
Jun, 2020	Member, Organizing Committee, World Congress of Bioethics Philadelphia, PA
Jun, 2020	Member, Organizing Committee, National Human Genome Research Institute ELSI Congress New York, NY

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Research Publications, peer reviewed (print or other media):

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Ethics Rounds: Life-Threatening Illness and the Desire to Adopt. Kennedy Inst Ethics J 15(4): 385-93, 2005.

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